American Type Culture Collection

12301 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301)231-5520 Telex: 898-055 ATCCNORTH • FAX: 301-770-2587

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Chiron Corporation
Attention: Karen Van Note
4560 Horton Street
Emeryville, CA 94608-2916

Deposited on Behalf of: Chiron Corporation (Case No. #2630.2)

Identification Reference by Depositor:	ATCC Designation
Hybridoma 5D12, CMCC 11068	HB 11339
Hybridoma 3C6, CMCC 11067	HB 11340
Hybridoma B7-24-E1G4, CMCC 11060	HB 11341

The deposits were accompanied by: __ a scientific description __ a proposed taxonomic description indicated above.

The deposits were received May 6, 1993 by this International Depository Authority and have been accepted.

AT YOUR REQUEST:

X We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years after the date of deposit, and for a period of at least five years after the most recent request for a sample. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested May 13, 1993. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Bobbie A. Brandon Date: May 21, 1993

Bobbie A. Brandon, Head, ATCC Patent Depository

cc: Mr. Kenneth Goldman

America Type Culture Collection

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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Chiron Corporation
Attention: Karen Van Note
4560 Horton Street
Emeryville, CA 94608-2916

Deposited on Behalf of: Chiron Corporation (Case No. 0925.003)

Identification Reference by Depositor:	ATCC Designation
Hybridoma, 3A8, CMCC #11066	HB 12024

The deposit was accompanied by: ___ a scientific description ___ a proposed taxonomic description indicated above.

The deposit was received January 24, 1996 by this International Depository Authority and has been accepted.

AT YOUR REQUEST:

X We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years after the date of deposit, and for a period of at least five years after the most recent request for a sample. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested January 30, 1996. On that date, the culture was viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Barbara M. Hailey

Barbara M. Halley, Administrator, ATCC Patent Depository

Date: February 6, 1996

cc: Paul Savereide

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N.73464A TJD/cm	99104709.3-2401/0945465
Anmelder/Applicant/Demandeur/Patentinhaber/Proprietor/Titulaire: CHIRON CORPORATION	

COMMUNICATION PURSUANT TO ARTICLE 115(2) EPC

Please find enclosed observations by a third party concerning the patentability of the invention of the above-mentioned patent application. That person is not a party to the proceedings before the EPO (Art. 115(1) EPC).

Under Article 115(2) EPC you may comment on the observations.

Formalities Officer
Tel. No. 089/2399 - 7548

A. Ramp

Ramp

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12
29. März 2004

Munich, March 29, 2004

Our Ref.: AV-2004-264 m2

EP 99104709.3 in the name of Chiron Co. entitled "Antagonistic monoclonal antibodies to human CD40"

Please find enclosed third party observations pursuant to Article 115 EPC.

I. Present claims

In their letter dated 27 January, 2004, the patentee submitted an amended set of claims 1-13.

Claim 1 recites a monoclonal antibody or fragment thereof capable of binding to a human CD40 antigen located on the surface of a human B cell, wherein the binding of the antibody or fragment thereof to the CD40 antigen prevents the growth or differentiation of the B cell.

Claim 2 is directed to the specific monoclonal antibodies 5D12 and 3C6. Claims 3 and 4 are dependent on claim 2 which recites these specific antibodies.

Claim 5 relates to a hybridoma capable of producing a monoclonal antibody having specificity for the CD40 antigen of a human B cell,

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wherein the binding of said monoclonal antibody to a human CD40 antigen expressed on the surface of a human B cell inhibits the growth or differentiation of the B cell.

Claims 6 and 7 recite the same specific antibodies of claim 2.

Claim 10 relates to aCD-40 antigen epitope immunoreactive with an anti-CD-40 monoclonal antibody.

Claims 8, 9 and 11-13 relate to 2nd medical indications using the above monoclonal antibodies or pharmaceuticals comprising these antibodies.

II. The pending claims cannot enjoy the 1st priority date

D1: Journal of Immunological Methods, vol. 152, no. 1, 31 July 1992 (1992-07-31), pages 15-23.(Cited International search report and EPO search report)

In the priority application USSN 07/910222 (filed on July 9, 1992), there is no description regarding the specific feature of the anti-CD40 antibody recited in claims 1 and 5, the specific use of the anti-CD40 antibody recited in claims 8, 9 and 11, the pharmaceutical composition recited in claims 12 and 13, and the specific CD40 antigen epitope recited in claim 10. That is, USSN 07/910222 never discloses an antibody which can prevent the growth or differentiation of B cells.

Regarding the hybridoma claims (claims 5 to 7) and the claim reciting specific antibody clones (claim 2), there is no description of depository number of hybridomas producing monoclonal antibodies 5D12 and 3C6 in USSN 07/910222. Based on the description on page 81 of the present specification, the depository date of hybridoma 3C6 and 5D12 is May 6, 1993. The claimed invention cannot be enabled without the deposition of hybridomas.

Therefore, the effective application date which is the date to judge the novelty and inventive step is the international filing date, July 8, 1 993, or at the earliest, May 28, 1993 (filing date of 3rd priority application).

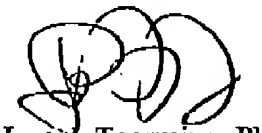
III. Lack of patentabilty over de Boer et al (D1)

D1, which was published before May 28, 1993, discloses the anti-CD40 antibodies termed 3A8, 3C6, 5D12 and 5H7 and hybridomas producing these antibodies. D1 also describes that these monoclonal antibodies can be bound to CD40 on B cells (see page 21, left column, lines 12-15; Table 11). CD40 antibodies with the same names and hybridomas producing these same antibodies are described in the present specification.

Present claims 2, 6 and 7 are not novel over D1 since the claimed antibodies and hybridomas are indistinguishable from those disclosed in D1. Claims 1 and 5 also lack novelty over D1, since claims 1 and 5 comprise 5D12 and 3C6 antibodies and hybridomas, respectively. Claims 3 and 4 are anticipated by D1, since humanized antibody and antibody fragments such as Fab' are well-known variations of the monoclonal antibody

At the time of filing the present application, testing B cell proliferation activity was a routine experiment for characterization of the anti-CD40 antibody. Therefore, the person skilled in the art can readily find the specific feature of the 5D12 and 3C6 antibodies, described in D1. Therefore, claims 8, 9, 11, 12 and 13 are readily conceived based on the descriptions of D1.

Regarding claim 10, the third party observer would like to point out that no specific CD40 antigen epitope is shown in the specification.



Joseph Taormino, Ph.D.
Association No. 151

Encl.:
D1: Journal of Immunological Methods, vol. 152, no. 1, 31 July 1992